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**The SensaScope®: a new hybrid video intubation style for regular and
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The SensaScope®: a new hybrid video intubation stylet for regular and difficult intubation

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Short running title

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Abstract

The recently developed SensaScope® is a hybrid intubation stylet that has been designed and developed according to our clinical requirements for a safe, easy to handle and effective video-assisted intubation. The attribute “hybrid” derives from the fact that the shaft of the instrument is combined by both, a rigid as well as a flexible part. Its S-shaped rigid shaft enables a very intuitive handling by one hand only, thus leaving the left hand free to operate a conventional laryngoscope. The tip of the device can be bended via a steering handle in a similar fashion as fiber optic endoscopes. Due to these attributes, the SensaScope® became a very versatile and effective tool to master the unanticipated difficult intubation in anesthetized and paralyzed patients. For this reason, in our institution it has been included as the first line technique into our local failed intubation algorithm. The first clinical experience with the device and its standardized technique of use produced encouraging results; the success rate for novices was found to be at 97% (in 194 of 200 patients) of all intubation attempts in both, patients who were rated as having normal (84.5%) as well as showing difficult intubation conditions (15.5%). The technical development, the way of using the device, the suitable indications and limitations are discussed.

Purpose and first experiences

Since the first prototype of the SensaScope® (Acutronic Medical Systems AG, Hirzel, Switzerland) was released in 2006,¹ it has been extensively used in our department in hundreds of elective cases. An approval of the institutional Ethics Committee for the clinical use of the equipment in surgical patients (with informed consent in elective cases and without informed consent in emergency cases) has been obtained. Due to direct laryngoscopy which is part of the standardized technique of use, the laryngoscopic view of the larynx can be compared to the endoscopic view in the same patient by the same operator. To obtain a first estimation of success rate, we found in the first 200 uses of the device 6% of direct laryngoscopic laryngeal views with grade 3 or 4 according to the Cormack & Lehane classification.² This corresponds well with the reported frequency of difficult laryngoscopy in the literature.³ In 294 patients, intubation was easily performed with the SensaScope®, which always delivered a full endoscopic view of the glottis (grade 1 according to Cormack & Lehane) as well as of the entire intubation pathway during advancement of the scope. In 2 cases a posteriorly adherent epiglottis that could not be elevated from the posterior pharyngeal wall necessitated a somewhat different approach: The endoscope had to be advanced first into the oesophagus and the view to the glottis could only be achieved while slowly retracting the device strictly in midline with a slightly elevated tip. In these cases, intubation lasted more than 60 seconds, but could be completed in less than 2 minutes. An intubation duration > 60 and < 120 seconds occurred in other 4 patients, where abundant secretions fogged the optic and required suction and cleaning of the instrument's tip. In no patient pulse-oximetric saturation fell below 90% or any other airway related problem occurred. However, these observations certainly need to be substantiated by further prospective investigations. By now they at least indicate the high probability that the device is a useful tool in the management of both, the regular and the difficult intubation.

Limitations of the device

As any other endoscopic instrument, the SensaScope® requires space to provide an image on the video screen. Inability to elevate the tongue base (e.g. after extensive operations in the mouth floor region or radiation therapy) or abundant secretions, bleeding or vomiting preclude its use and non-visualizing means of airway securing should be chosen instead. Also reduced mouth opening to less than 2 cm might be a hindrance, however, as for the regular technique, a distance allowing the passing of a laryngoscope blade is sufficient to apply the SensaScope® which is less than necessary for conventional intubation. We have encountered difficulties to intubate with the SensaScope® only in 2 patients with posteriorly adherent epiglottis; a problem that could be solved with a specific technique by first advancing the scope into the oesophagus and secondarily retracting it till the laryngeal entrance appeared on the screen. Another limitation of the SensaScope® is that it cannot be used via a nasal approach; the device is designed exclusively for oral intubation only.

The new “stand alone” SensaScope®

As a result of 2 years of development and testing of intermediate prototypes, a “stand alone” type SensaScope® has been created which has not to be combined with external light source and video camera units. The version is composed of the endoscope with an inbuilt camera and light source that has to be only connected to the video monitor via a connecting interface in a small box. The new SensaScope® has no eyepiece anymore and instead of two heavy cables (one for the video signal and another for the cold light) there is only a lean cable to the video interface. This configuration became possible because a miniaturized CCD chip became available and could be fitted into the tip of the device, as well as a tiny LED chip to produce the necessary light. By becoming lighter and having only one slender cable, manoeuvrability and comfort of use increased considerably. A more important benefit of this modification resulted in a grossly improved image quality on the monitor. The shape of the image is now rectangular and completely fills the screen of the monitor as compared with the relatively small circular image in the middle of the video screen deriving from the attached camera. Even more impressive is the difference in the image resolution; in the old prototype the image was composed by a fiber optic bundle that presented the usual unsubtle pixels, while the new device provides a brilliant image quality (**Figure 1**).

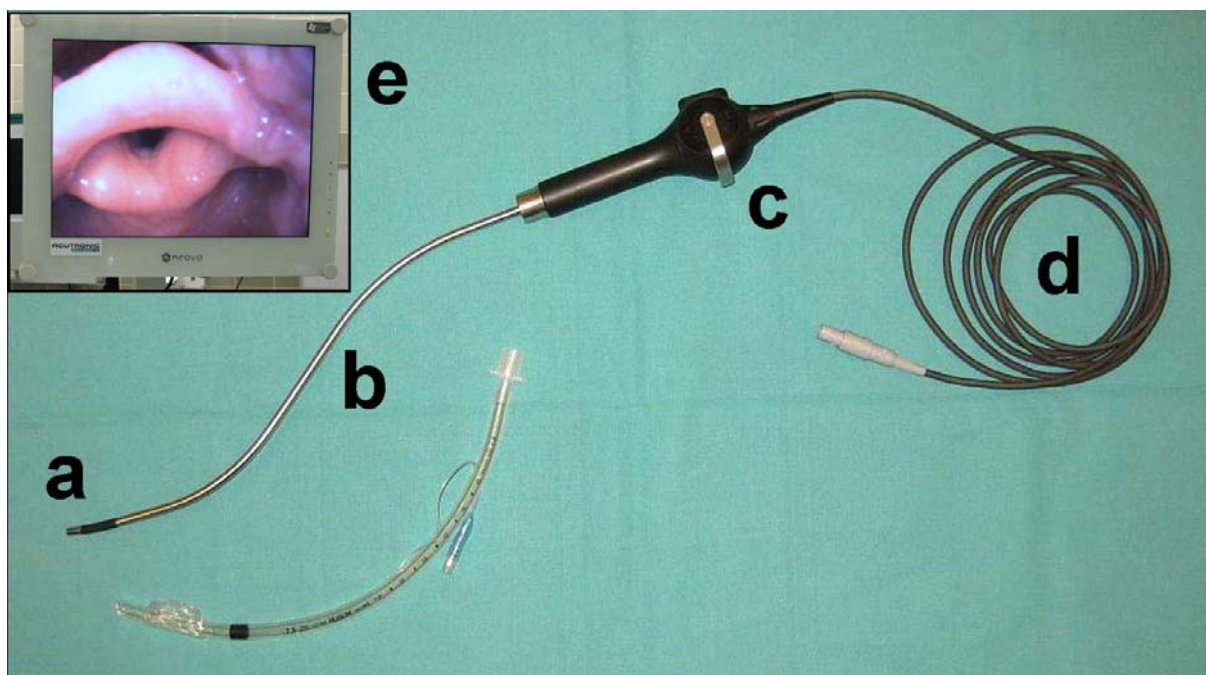


Figure 1: The SensaScope® is composed by a) a steerable tip, b) a rigid sigmoid shaft with metallic surface, c) a handle piece with a steering lever, and d) a lightweight 2 m long cable to be connected to the video interface. The inset e) shows the monitor display of the image transmitted from the tip of the endoscope.

The most important advantage of the new SensaScope® is the ease of handling. The early “modular” version had to be connected to the light source and the camera had to be attached to the eyepiece. This was followed by searching for the right focus, finding the correct axial alignment and acquiring the white balance. Even with gaining routine by repeated use, these preparations needed up to 3 minutes – which in unexpected difficult airway situations may cause a relevant delay in solving the problem. The new SensaScope® became lightweight and simple to use. To operate the system one only has to connect the sole cable to the video interface and to press the start button. Then the system is ready to use. The light intensity can be modified with a plus/minus switcher which is included in both, the handle of the stylet as well as in the video interface. This feature might be especially relevant in pre-hospital use of the device, where light conditions might be very variable and eventually less favourable. The available experience with the device showed that even novice anesthetists could get accustomed with the handling of the endoscope. Usually 4 attempts were sufficient to attain a successful and expedient performance with the SensaScope in normal airway situations. However, there is yet no information available about the success rate of the device in difficult airway situation handled by unexperienced users. The available data with experienced users shows no relevant difference in the success rate or intubation time between easy and difficult airway conditions.

What remains unchanged?

The intubation technique as described in the first publication remains unchanged.¹ In particular, it has to be emphasized that the proper use of the device requires direct laryngoscopy. In the anesthetized and paralyzed patient lying in supine position, the hypopharynx is occluded and there is no free space to enable viewing with an endoscopic device (**Figure 2**).

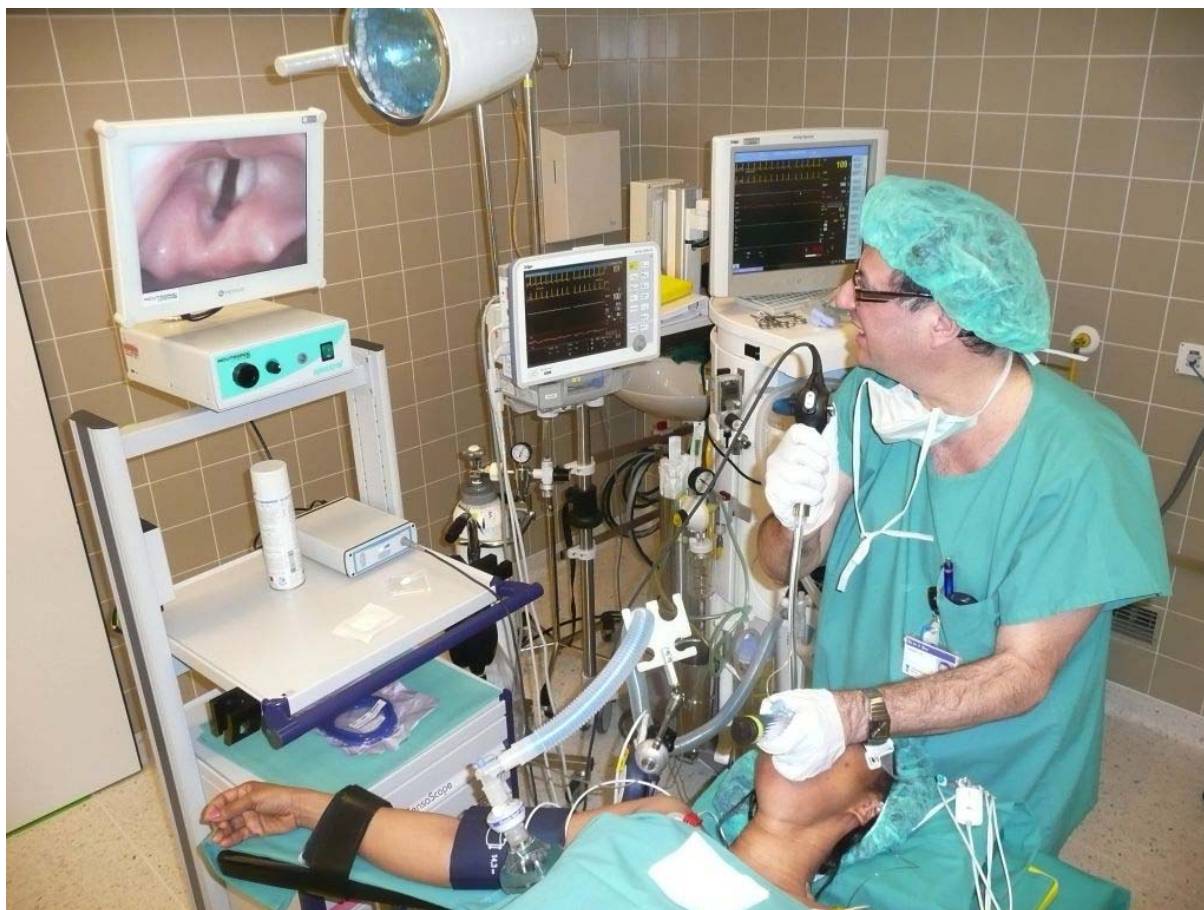


Figure 2: Clinical setting during intubation with the SensaScope®.

Thus, elevation of the base of the tongue is mandatory, even if a direct laryngoscopic view cannot be achieved. The exact definition of the actually accepted indication for the SensaScope® in our institution is now “the unexpected difficult intubation in anesthetized and paralyzed patients who cannot be expected to return to wakefulness and spontaneous ventilation in due time and who require a secure airway”.

Future directions

The observed ease of visualisation of the glottis even in difficult direct laryngoscopy situations leads to the assumption that the SensaScope® might be also suitable to deal with the expected difficult airway. In this case it would challenge the actually established priority of the flexible fiber optic intubation, which is justifiably recognized as the gold standard.⁵ A first confirmation of this assumption has recently been found by Greif et al. who successfully have used the device in 13 cases of expected or even confirmed difficult airway, while adopting an awake or slightly sedated approach.⁶ While at this moment, the suitability of the flexible fiber optic in awake or lightly sedated patients who still have spontaneous breathing remains unquestioned, the SensaScope® might compete and eventually replace it in the elective anesthetized fiber optic intubation. This assumption is not only based on several cases that occurred to us accidentally and were easily mastered with the SensaScope®, but also on the plausibility of the fact that a predominantly rigid stylet can be handled in a more intuitive way than a floppy device, where the tip does not automatically follow movements exerted at its proximal end. In contrast, no such statement can be made concerning the awake intubation with the SensaScope®, since until now there is no such experience available.

Another possible, and yet to be tested indication of the SensaScope® could be the rapid sequence induction, where a higher probability of success might be expected if the whole procedure happens under fully visualized conditions, independently of the quality of the resulting direct laryngoscopic view.

Recently a protective waterproof sleeve (SensaSleeve™, Acutronic Medical Systems AG, Hirzel, Switzerland) became available, which can be mounted on the SensaScope® covering its entire shaft. When covered by the sleeve, the endotracheal tube has to be treated with a silicone spray in order to allow smooth railroading. The tip of the sleeve is transparent and when it closely adheres the scope tip, the image quality as well as the light intensity remains nearly unaffected. With this configuration, after use the SensaScope® must not anymore be immersed into a disinfectant for 45 minutes; after careful removal of the sleeve, a quick swabbing of the shaft with disinfectant-moistened gauze is sufficient. However, such a single use sleeve costs recently about 18 \$ and the user has to decide whether he should save the costs of a sleeve or of the 45' time and effort for a regular disinfection cycle.

In conclusion we can state that based on the available experience with intubations of regular and difficult cases with the SensaScope®, there is strong sign that this device is well suitable for management of the unexpected difficult intubation. Additionally there is a certain outlook of extending the indications to other scenarios such as the elective anesthetized fiber optic intubation in patients with suspected airway difficulty but possible face mask ventilation. Another possible beneficial use might be in the rapid sequence intubation where the availability of a continuous visualisation of the intubation pathway and the resulting location of the endotracheal tube might be beneficial.

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